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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,628	11/23/2001	E. James Squires	6580-234	8447

7590

09/26/2003

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 09/26/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,628

Applicant(s)

SQUIRES ET AL.

Examiner

David J. Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

- [1]** Claims 1-26 are pending in the application.

Election/Restrictions

- [2]** Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I.** Claim(s) 1-6, drawn to a method for determining the susceptibility of a male pig to developing boar taint, classified in class 435, subclass 4.
- II.** Claim(s) 7-10, drawn to a method for reducing or preventing boar taint by enhancing the activity of a CYP2E1 enzyme, classified in class 435, subclass 189.
- III.** Claim(s) 7 and 11-13, drawn to a method for reducing or preventing boar taint by enhancing the activity of a sulfotransferase enzyme, classified in class 435, subclass 193.
- IV.** Claim(s) 7 and 14-16, drawn to a method for reducing or preventing boar taint by decreasing the activity of a glucuronyl transferase enzyme, classified in class 435, subclass 193.
- V.** Claim(s) 17-19, drawn to a method for screening for a substance that enhances the activity of CYP2E1, classified in class 435, subclass 25.
- VI.** Claim(s) 20-22, drawn to a method for screening for a substance that enhances the activity of sulfotransferase, classified in class 435, subclass 15.
- VII.** Claim(s) 23-25, drawn to a method for screening for a substance that inhibits the activity of glucuronyl transferase, classified in class 435, subclass 15.
- VIII.** Claim(s) 26, drawn to a composition for reducing or preventing skatole metabolism by administering a substance that increases the activity or expression of CYP2E1 enzyme, classified in class 514, subclass 789.

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- IX.** Claim(s) 26, drawn to a composition for reducing or preventing skatole metabolism by administering a substance that increases the activity or expression of sulfotransferase, classified in class 514, subclass 789.
- X.** Claim(s) 26, drawn to a composition for reducing or preventing skatole metabolism by administering a substance that decreases the activity or expression of glucuronyl transferase, classified in class 514, subclass 789.
- [3]** The inventions are distinct, each from the other because:
- [4]** The methods of Groups I-VII are independent as they comprise different steps, utilize different products and/or yield different results.
- [5]** The compositions of Groups VIII-X are unrelated to the method of Group I as the compositions of Groups VIII-X are neither made nor used by the method of Group I.
- [6]** The compositions of Groups VIII-X and the methods of Groups II-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The compositions of Groups VIII-X can be used for methods other than the methods of Groups II-IV such as for reducing or preventing skatole metabolism. The compositions of Groups VIII-X can be used for methods other than the methods of Groups V-VII such as for screening substances that enhance CYP2E1 and sulfotransferase activity or decrease glucuronyl transferase activity.
- [7]** The compositions of Groups VIII-X are distinct as each of the compositions elicits a different effect and no single composition of Groups VIII-X would render the others obvious to one of ordinary skill in the art.
- [8]** MPEP § 803 sets forth two criteria for restricting between patentably distinct inventions – 1) the inventions must be independent or distinct and 2) there must be a serious burden on the examiner. MPEP § 803 states, "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate

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status in the art, or a different field of search as defined in MPEP § 808.02". Because the inventions of Groups I-X are distinct for the reasons given above and each of the inventions requires a separate patent and non-patent literature search, restriction for examination purposes is proper.

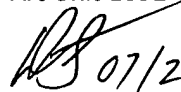
[9] It is noted that claims 7 and 26 will be examined only to the extent the claims read on the elected subject matter.

[10] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[11] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

 07/24/03